DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
U.S. Food and Drug Administration Chicago District Office 550 W. Jackson Blvd Chicago, IL 60661 (312) 353-5863 Industry Information: www.fda.gov/oc/industry	10/6/2025 - 10/14/2025
	FEI NUMBER 3003983334

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Lucas G. Guarnaccio, Director, Manufacturing Operations

FIRM NAME	STREET ADDRESS
Medline Industries, LP	1710 S. Lakeside Drive
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Waukegan, IL 60085	Drug Manufacturer

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

Your firm's quality control unit failed to exercise its responsibility to ensure drug products manufactured are in compliance with CGMP, and meet established specifications for identity, strength, quality, and purity.

Specifically,

A. Your Quality Unit is not ensuring that changes which can impact product quality are enforced. Particularly, where employee behavior in the production areas are a known issue.

i. OOS25-003 which was initiated on 2/28/2025 to investigate B. cereus that was again detected during product release testing of [redacted], batch [redacted], identified "several instances" of poor aseptic behavior as a potential root cause.

ii. OOS25-007 which was initiated on 06/04/2025 after B. cereus was again detected during finished product release testing of [redacted], batch [redacted]. Poor aseptic behavior. was the primary root cause identified which had led to direct product contamination of [redacted], Batch [redacted].

Although you initiated CAPAs as a result of each of these investigations, your quality unit failed to ensure that employees follow production room behavior and aseptic practice procedures.

B. The quality control unit lacks authority to fully investigate errors that have occurred. Specifically, your firm's quality control unit failed to exercise adequate oversight and implement systematic corrective measures to prevent the recurrence of repetitive quality issues:

i. Inadequate Response to Repetitive Deviations - The quality unit, acknowledged the occurrence of repetitive

[redacted]

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	Gabriel Bermudez Picart -S Digitally signed by Gabriel Bermudez Picart -S Date: 2025.10.14 16:24:46 -05'00' Michele L. Glendenning -S Digitally signed by Michele L. Glendenning -S Date: 2025.10.14 16:26:50 -05'00'	Michele L. Glendenning, Investigator Gabriel Bermudez-Picart, Investigator	10/14/2025

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deviations but failed to implement systematic corrective and preventive actions (CAPA) to address underlying root causes. Review of deviation records from 01/2025- 10/2025 (19870, 19919, 19950, 20304, 20305, and 20416) revealed a pattern of similar non-conformances that were addressed individually without comprehensive investigation into systemic issues.

ii. Deficient Process Control Procedures - Procedure RC-27 for [redacted] tracking was modified on August 30, 2025; however, the revision did not adequately address the fundamental deficiencies in the review process that contributed to ongoing compliance failures. The procedure lacks provisions for second person verification of the [redacted] cleaning and continues to rely on [redacted] documentation review, which is insufficient for preventing non-conforming product from advancing through manufacturing operations. Additionally, documentation review revealed that quality assessment of critical process steps is conducted [redacted] rather than during critical process steps, limiting the quality unit's ability to prevent deviations and ensure real-time compliance.

iv. Investigation records demonstrated that the quality unit's approach to deviation investigations focused on immediate corrective actions without conducting thorough root cause analyses to prevent recurrence of similar issues.

OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

A. After initially detecting and confirming an OOS (OOS-23-007) for objectionable microorganism B. cereus in release testing of [redacted] in batch [redacted], initiated June 21, 2023, your firm has continued to manufacture and market batches of [redacted] without fully determining root cause for your failure to meet specifications, and with your 'validated' manufacturing process showing evidence that it is not capable of consistently producing quality product. Your investigation concluded, "The most likely root cause was identified as contamination during handling of the raw materials, most likely coming from dirt and

[redacted]

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general build-up on the exterior of the [redacted]."

Including this event your firm has detected B. cereus in finished product 6 times between 2023 and January 2025. These issues were discussed with your firm management during the previous inspection. Since January 2025 your firm has had an additional 4 B. cereus events affecting finished product and a cosmetic bulk solution raw material. Additionally, there have been 5 environmental monitoring recoveries of B. cereus in your Line [redacted] and Line [redacted] 'cleanrooms' between 06/06/2025 and 08/01/2025. Furthermore, your firm also obtained 3 B. cereus recoveries through contact plating as part of investigatory practices. These additional recoveries are in addition to the environmental monitoring recoveries.

i. OOS25-003 was initiated on 2/28/2025 to investigate B. cereus that was again detected in finished drug products, specifically, found during product release testing of [redacted], batch [redacted]. This investigation could not identify a definitive root cause but instead indicated that 5 probable root causes had been identified. Your firm has continued to manufacture and market batches of [redacted] without fully determining root cause for your failure to meet specifications, rejecting this particular batch but releasing other batches when release testing did not detect B. cereus. It should be noted that contact plates were taken to isolate locations where the contamination could have originated from. The following areas within [redacted] had recovered B. cereus growth: the bottom of the [redacted], the floor outside of the [redacted] door, and the [redacted]).

ii. You initiated OOS25-007 on 06/04/2025 after B. cereus was again detected in finished drug products, specifically, during finished product release testing of [redacted], batch [redacted]. Your investigation identified through camera footage review objectionable behavior by one operator (Employee #[redacted]. The employee was observed moving through a series of inappropriate behaviors in the cleanroom. Your firm has continued to manufacture and market batches of [redacted] after your failure to meet specifications, rejecting this particular batch but releasing other batches when release testing did not detect B. cereus. Based on these behaviors being directly product contact related and the observed times of these behaviors

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being immediately before the timestamp of the failing finished good pack, the OOS investigation determined this to be the primary root cause for the micro contamination failure.

iii. You initiated OOS25-0010 on 09/22/2025 after detecting B. cereus again in drug products specifically, during finished product release testing of [redacted] batch [redacted]. This investigation is currently still being drafted, therefore root cause has yet to be determined.

iv. You initiated OOS25-011 on 09/22/2025 after detecting Chryseobacterium indologenes during finished product release testing of [redacted] batch [redacted]. This investigation is currently still being drafted, therefore root cause has yet to be determined.

B. Your firm did not conduct adequate deviation investigations, as evidenced by insufficient documentation and incomplete corrective actions. Specifically,

i. Deviation 19870 (Open Planned Cleaning): Documentation failed to demonstrate that [redacted] were properly cleaned as required by established procedures. No evidence was provided to verify completion of cleaning procedures.

ii. Deviation 19919 ([redacted] Disinfection): Missing operator signatures on critical disinfection steps were identified. While [redacted] requirements were met, [redacted] disinfection was not performed. Corrective action was limited to operator retraining only, with no preventive measures implemented and no QA verification of corrective action effectiveness.

iii. Deviation 19950 (Missing Disinfection Signatures): Required disinfection procedures could not be verified due to missing documentation. Corrective action was again limited to retraining without preventive measures.

iv. Deviation 20304 [redacted] Disinfection Non-Compliance): This recurring issue related to previous deviations indicated a systemic problem.

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C) Your firm failed to thoroughly review production records to ensure that no errors have occurred, or if errors have occurred, that they have been fully investigated, in that: Specifically:

Delayed Deviation Reporting: Deviation 20651 was not initiated until April 2025, approximately two months after the actual occurrence on February 12, 2025, when an incorrect cleaning agent [redacted]) was used instead of the specified [redacted] during [redacted] cleaning procedures. Following a positive Bacillus cereus environmental monitoring result on Line [redacted] (February 27, 2025), your firm failed to promptly identify the potential relationship between the improper cleaning procedure on Line [redacted] and the EM contamination event on line [redacted]
Initiate an investigation in a timely manner, or conduct a comprehensive investigation to determine root cause; and implement immediate corrective actions to address the contamination risk. Additionally, no preventive actions were implemented to prevent recurrence of the improper cleaning agent usage, despite the potential connection to microbial contamination that required investigation expansion to multiple production lines due to contamination risk.

OBSERVATION 3
Your firm failed to establish adequate procedures to prevent contamination of drug product components during manufacturing operations. Specifically,

During a walkthrough of the manufacturing area on October 6, 2025, FDA investigators observed operators engage in practices that could result in contamination of drug product components. As a result, we requested camera footage of the production activities for [redacted] Batch [redacted] Operators were observed to:
(a) Place his foot on a [redacted] used to transfer [redacted] to the [redacted] machine, pushing it toward the other operator who then also placed his foot on top of the [redacted]
(b) Push down the contents of a trash bin located in close proximity to the [redacted]. One portion of video also shows this same behavior but additionally the operator grabbed the open end of the trash bag, raised it slightly out of the trash can and shook it up and down.

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(c) Proceed to manipulate the [redacted] during set-up procedures without changing or sanitizing his [redacted] after these activities.
(d) Touching their face and then almost immediately grabbing a [redacted] and transferring it to the [redacted].
(e) While removing the [redacted] of the [redacted] the [redacted] fell on the floor and operators hastily gathered the [redacted] off the floor, wadding it in their hands and pushing it into a nearby trash can.

OBSERVATION 4
Written procedures are not established or followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

A. During the inspection, our investigators observed poor cleaning procedures performed in your Line [redacted] ISO [redacted] production cleanroom that were previously videotaped at your facility on 10/04/2025. Machine operators were observed failing to follow written procedures outlined in SOP [redacted]-00005, [redacted] Cleaning Procedure for Production Areas and Equipment for cleaning floors and equipment in Line [redacted] prior to the production of [redacted], product code [redacted], batch [redacted]. Cleaning staff was observed:
i. Not overlapping mop strokes to ensure the cleaning/disinfectant is evenly applied on the entire surface of the floor.
ii. Failing to periodically check mop heads for evidence of drying/soiling.
iii. Failing to use "Place and Pull" floor mopping method.
iv. The operator failed to follow the Standard Operating Procedure (SOP) requirement to clean [redacted] Instead, the operator began cleaning at [redacted] Station [redacted] of the [redacted] near the safety cage and proceeded toward the outside of the room, which is contrary to the established procedure.

B. Your procedure [redacted]-00005, Cleaning Procedure for Production Areas and Equipment lacks sufficient

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instructions on how to clean equipment and room areas such as production floors. For example, during the inspection, our investigators observed poor cleaning procedures performed in your ISO [redacted] production cleanrooms that were previously videotaped at your facility (Production Line [redacted] on 10/04/2025. Production operators were observed:
(a) Sloshing liquid on the floor toward floor drains using a squeegee in a manner that caused the liquid on the floor to splash onto equipment.
(b) Walking over cleaned floor areas before the contact times for the [redacted] application had been reached.
(c) Moving equipment onto cleaned floor areas before the contact time for the [redacted] solution application had been reached.
(d) Failing to periodically change to a clean [redacted] wipe while removing disinfectant [redacted] on [redacted] equipment surfaces.

Your written cleaning procedures do not address the proper way to avoid these behaviors. These behaviors represent a risk of contamination to finished drug products manufactured at your facility.

OBSERVATION 5
Buildings and facilities used in the manufacture, processing, packing, or holding of a drug product shall be maintained in a good state of repair. Specifically,

1. Multiple holes were observed in the line [redacted] production room floor that present cleaning challenges and create potential harborage sites for objectionable microorganisms. These floor defects may compromise the ability to maintain adequate sanitary conditions in the manufacturing environment.
2. Holes in the line [redacted] gowning room floor were observed that remained unrepaired following completion of a work order to relocate a bench. These floor holes were not addressed until brought to management's attention during the current FDA inspection, indicating inadequate facility maintenance procedures.

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	Gabriel Bermudez Picart -S Digitally signed by Gabriel Bermudez Picart -S Date: 2025.10.14 16:25:21 -05'00' Michele L. Glendenning -S Digitally signed by Michele L. Glendenning -S Date: 2025.10.14 16:27:32 -05'00'	Michele L. Glendenning, Investigator Gabriel Bermudez-Picart, Investigator	10/14/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or

2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."